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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jean-Marc Beraud

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,799	Applicant(s) BERAUD, JEAN-MARC	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 5/22/08.

Specification

2. The applicant's amendment to the specification and abstract filed on 5/22/08 is acceptable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 17-19 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0156489 to Gellman et al.

(claim 17) Gellman discloses a device for placing a reinforcing tape in a tissue of the human body, comprising an introducer including: an elongated flexible body **20** extending along a longitudinal axis and having two ends (see Fig. 8A), each of said ends provided with a pulling means (**201,202**); a cavity **185** provided in said flexible body between said ends for receiving a reinforcing tape **10**, the cavity defined by walls within the body (see Fig. 8A); and means for cutting the body into two portions separable by pulling on the pulling means, the cutting means comprising at least one

aperture provided in the flexible body into the cavity and extending transversally to the longitudinal axis (see Fig. 8I for the aperture), the aperture affecting more than half of the circumference of the walls of the cavity, so as to leave only a connecting wall (defined by sections 150A and 160A) between portions of the flexible body delimited by the aperture, the aperture being capable for allowing passage of a cutting tool between the tape received in the cavity and the connecting wall.

(claim 18) The aperture is constructed and arranged to allow placement of the tape in the cavity.

(claim 19) The cutting means comprises at least two apertures positioned facing each other (see Fig. 8I, the envelope has two apertures on either side of the top sections 150A and 160A).

(claim 22) The device comprises a tape **10** freely positioned inside the cavity.

(claims 23 and 24) The device comprises an elongated perforator guide or trocar, having a first end arranged for introduction into the body of a patient and an opposite end provided with a handle (see Fig. 19A), wherein the perforator guide has a portion having an arcuate shape in a plane (see Fig. 19B).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al., as applied in the rejections above.

(claim 20) The embodiment taught by Gellman in Fig. 8A-8I discloses all the limitations of the claims except for the device having a series of perforations for sterilization. However, Gellman discloses in Fig. 3A-3B an elongated body having apertures/perforations along its length. The apertures are used to delivery drug into the tissues (paragraph [0144]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the embodiment shown in Fig. 8A-8I of Gellman to also include the apertures as it would allow the device to delivery drugs to the tissues. The apertures would also be capable of allowing sterilization of the device.

(claim 25) Gellman discloses all the limitations of the claims except for the arcuate portion of the perforator guide extends over an angular sector larger than 140°. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited angle since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

(claims 26-28) Gellman discloses all the limitations of the claims except for the arcuate portion of the perforator guide extends over an angular sector between 150° and 170°; the arcuate portion of the perforator guide has a radius of curvature between 30 and 60 mm for a portion of the perforator guide extending between the handle and the first end, wherein the radius of curvature is between 40 and 50 mm. However, it

would have been obvious one to one of ordinary skill in the art to arrive at the recited ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(claims 29-32) Gellman discloses all the limitations of the claims except for the perforator guide having a helicoidal shape at the first end, wherein the shape is a portion of a helicoidal coil extending over an angle between 180° and 360°, wherein the shape is a portion of a helicoidal coil extending over an angle between 255° and 270°, wherein the coil of the perforator guide has a radius of curvature between 20 mm and 40 mm with a pitch between 15 mm and 25 mm. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of Gellman to have a helicoidal shape since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It also would have been obvious to arrive at the recited ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al., as applied in the rejections above, and in further view of US 6,612,977 to Staskin et al.

Gellman disclose all the limitations of the claims except for the device having semi-rigid needles integral with the elongated body. However, Staskin a device for

placing a reinforcing tape in a tissue of a human body, the device having semi-rigid needles **60** attached to pulling portions of an elongated body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gellman to have semi-rigid needles attached to the elongated body as it would allow the delivery of the elongated body into the human body without the use of a separate piercing tool. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to have the needles be integral with the ends of the elongated body since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

8. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. ('489, as applied in the rejections above, and in further view of US 2002/0055748 to Gellman et al ('748).

Gellman '489 discloses all the limitations of the claims except for the use of a removable tubular sleeve with a complementary shape to that of the perforator guide, constructed and arranged for engagement onto the perforator guide and to remain in the body of the patient after removing the perforator guide, so as to define a tunnel for the passage of pulling means of the introducer, wherein the tubular sleeve has a length greater than a useful length of the perforator guide and comprises a side aperture for placement of the perforator guide, the side aperture being located at a distance from a free end of the sleeve less than or equal to the useful length of the perforator guide.

However, Gellman '748 discloses such a removable tubular sleeve that remains in the body of the patient so as to define a tunnel for the passage of the introducer (see Fig. 13). Therefore, it would have been obvious to one of ordinary skill in the art to modify the system of Gellman '489 to include a removable tubular sleeve as taught by the '748 reference since it would allow for an easier deployment of the introducer into the cavity of the human body.

Response to Arguments

9. Applicant's arguments with respect to claims 17-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773